

Notice of Allowability

Application No.

09/471,255

Examiner

Ginny Portner

Applicant(s)

HAMEL ET AL.

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1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/15/05.
2. ☒ The allowed claim(s) is/are 16, 18-20, 25,34-35, 39-50.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>attached</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>7/05</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

1. An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on March 9, 2006 requested an extension of time for 1MONTH(S) after filing a Notice of Appeal; and authorized the Director to charge Deposit Account No. 50-0417 the required fee for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

18. (Currently amended) An isolated polypeptide comprising the amino acid sequence consisting of SEQ ID NO :2.

19. (Currently amended) An isolated polypeptide comprising the amino acid sequence consisting of amino acids 2 to 1039 of SEQ ID NO :2.

20. (Currently amended) An isolated polypeptide comprising the amino acid sequence consisting of amino acids 21 to 1039 of SEQ ID NO :2.

34. (Currently amended) A vaccine composition comprising a polypeptide having at least 95% sequence identity with a polypeptide comprising the amino acid sequence consisting of amino acids 2 to 1039 of SEQ ID NO :2, wherein said polypeptide elicits a protective

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antistreptococcal immune response in an individual when administered to the individual, and a pharmaceutically acceptable adjuvant.

35. (Currently amended) A vaccine composition comprising a polypeptide having at least 95% sequence identity with a polypeptide comprising the amino acid sequence consisting of amino acids 21 to 1039 of SEQ ID NO :2, wherein said polypeptide elicits a protective antistreptococcal immune response in an individual when administered to the individual, and a pharmaceutically acceptable adjuvant.

43. (Currently amended) An isolated polypeptide comprising at least 95% sequence identity to amino acids 521 to 1039 of SEQ ID NO :2, wherein said polypeptide elicits a protective antistreptococcal immune response in an individual when administered to the individual.

44. (Currently amended) An isolated polypeptide comprising at least 95% sequence identity to amino acids 800 to 1039 of SEQ ID NO :2, wherein said polypeptide elicits a protective antistreptococcal immune response in an individual when administered to the individual.

45. (Currently amended) An isolated polypeptide comprising at least 95% sequence identity to amino acids 21 to 800 of SEQ ID NO :2, wherein said polypeptide elicits a protective antistreptococcal immune response in an individual when administered to the individual.

46. (Currently amended) An isolated polypeptide comprising at least 95% sequence identity to amino acids 472 to 1039 of SEQ ID NO :2, wherein said polypeptide elicits a protective antistreptococcal immune response in an individual when administered to the individual.

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47. (Currently amended) A vaccine composition comprising a polypeptide having at least 95% sequence identity to amino acids 521 to 1039 of SEQ ID NO :2, and a pharmaceutically acceptable carrier, wherein said polypeptide elicits a protective antistreptococcal immune response in an individual when administered to the individual.

48. (Currently amended) A vaccine composition comprising a polypeptide having at least 95% sequence identity to amino acids 800 to 1039 of SEQ ID NO :2, and a pharmaceutically acceptable carrier, wherein said polypeptide elicits a protective antistreptococcal immune response in an individual when administered to the individual.

49. (Currently amended) A vaccine composition comprising a polypeptide having at least 95% sequence identity to amino acids 21 to 800 of SEQ ID NO :2, and a pharmaceutically acceptable carrier, wherein said polypeptide elicits a protective antistreptococcal immune response in an individual when administered to the individual.

50. (Currently amended) A vaccine composition comprising a polypeptide having at least 95% sequence identity to amino acids 472 to 1039 of SEQ ID NO :2, and a pharmaceutically acceptable carrier, wherein said polypeptide elicits a protective antistreptococcal immune response in an individual when administered to the individual.

2. The following is an examiner's statement of reasons for allowance: The instantly claimed invention is directed to a Streptococcal polypeptide and specific immunogenic C-terminal fragments of the polypeptide that will elicit a protective immune response upon administration to an immunocompetant host. The instant Specification teaches the criticality of the conserved amino acid sequences in the variable region of the C-terminal of SEQ ID NO 2, to induce a

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protective immune response. The prior art of record does not teach, nor reasonably suggest the instantly claimed invention as now claimed.


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
March 17, 2006


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SUPERVISORY PATENT EXAMINER
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